

***REMARKS***

Claims 1-33 are pending in the application and were previously subject to a restriction requirement so graciously reconsidered and withdrawn by the Examiner. Of these claims, claims 15-20 were allowed, claims 12-14 were indicated as being allowable if placed in independent form as done in the preceding amendments, and claim 8 was rejected solely as lacking antecedent basis for one term, which has been obviated by the foregoing amendment to claim 1. Thus, by the foregoing amendments, claims 8 and 12-20 are either allowed or clearly in condition for allowance.

The rejections of the remaining claims are addressed in detail below and are believed to be obviated by the foregoing amendments and the following remarks, and thus claims 1-7, 9-11, and 21-33 are believed to also be in condition for allowance.

Claims 1 and 12 have been amended. Claim 1 has been amended to use consistent terminology within the claim, namely using "incapacitating agent". Claim 12 has been amended simply to place it into independent form incorporating all of the limitations of the base claim. No new matter has been added.

***Rejection Under 35 USC 112, second paragraph***

Claims 8 and 9 have been rejected under 35 USC 112, second paragraph as being indefinite in the lack of antecedent basis of the term "incapacitating agent". This rejection is obviated by the amendment to claim 1, from which both claims 8 and 9 depend, wherein the terminology has been rendered consistent to use the term "incapacitating agent".

Accordingly, reconsideration and withdrawal of this rejection is respectfully urged.

***Rejection Under 35 USC 102(b)***

Claims 27-30 have been rejected under 35 USC 102(b) as being anticipated by U.S. Patent No. 4,316,917 to Antoshkiw et al. Antoshkiw et al. was said to teach a stable carotenoid solution for food and beverages that (among a host of other ingredients) can comprise from about

25 to about 35% propylene glycol dicaprylate-dicaprate. The Examiner acknowledges that Antoshkiw et al. does not disclose the claimed molecular weight between 100 and 500 and the claimed vapor pressure below 1.0 mm HG, and concludes that these are inherent properties of propylene glycol dicaprylate-dicaprate. This rejection is respectfully traversed and is believed to be obviated in view of the following remarks.

Antoshkiw et al. is directed to a method of stabilizing a water insoluble high melting point carotenoid into a solution so that it can be utilized as a coloring agent for various foodstuffs, including water-based foodstuffs. The stabilized carotenoid solution comprises a carotenoid, an anti-oxidizer, a nonionic surfactant (the concentration of which is critical and must be between 25 and 35% by weight of the total solution), and a solubilizer comprising a mixture of one part of glycerol monocaprylate to 1.5 to 3.5 parts of propylene glycol dicaprylate-dicaprate.

The present invention is directed to a novel solvent system that is suitable for use over a wide range of temperatures and in a wide range of applications, and is particularly well suited for aerosol applications, where it allows ready dispersion of the active ingredients, is suitable for use with a wide range of propellants, and is of the claimed molecular weight and vapor pressure so as to impart precise targeting of the spray without undesirable blowback, even in windy and rainy conditions. The particular claimed molecular weight and vapor pressure of the solvent system are crucial for achieving these features and for achieving the wide range of operating temperatures and other desirable characteristics described in detail in the specification. The solvent system of the present invention has a molecular weight of 100 to 500, in contrast to the prior art solvents of water with a molecular weight of 18 and isopropyl alcohol with a molecular weight of 60. The solvent system of the present invention has a vapor pressure of less than 5.0 mm Hg, preferably less than 1.0 mm Hg, in contrast to the prior art solvents of water with a vapor pressure of 19 mm Hg and isopropyl alcohol with a vapor pressure of 33 mm Hg. The solvent system is preferably a mixture of propylene glycerol dicaprylate/caprate and glycerol tris (2-ethylhexanoate) exhibiting the claimed molecular weight and vapor pressure.

Antoshkiw et al. do not disclose or suggest the presently claimed solvent system of the present invention, nor the claimed formulation. For a reference to anticipate a claimed invention, it must show each and every feature of the claims. Antoshkiw et al. is directed to a stabilized solution of a carotenoid, not a solvent system or a formulation of an incapacitating agent in a solvent system. Furthermore, Antoshkiw et al. do not show a solvent system suitable for use over a wide range of operating temperatures having a molecular weight of at least 100 (claim 27), preferably from 100 to 500 (claim 28), nor do they show a solvent system having a vapor pressure less than 5.0 mmHg (claim 29), preferably less than 1.0 mm Hg (claim 30).

As noted above, the Examiner has deemed the claimed molecular weights and vapor pressures to be inherent properties of Antoshkiw et al.

Although it is possible to find anticipation from a single reference, for purposes of 35 U.S.C. § 102(a) or (b), even where an element of a claim is not expressly revealed in the allegedly anticipatory reference it requires that the element be inherent in the disclosed invention. *Tyler Refrigeration Corp. v. Kysor Industrial Corp.*, 777 F.2d 687, 227 USPQ 845 (Fed. Cir. 1985); *Verdegaal Brothers, Inc. v. Union Oil Co. of California*, 750 F.2d 947, 2 USPQ2d 1051 (Fed. Cir. 1987); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990); *Ex parte Novitski*, 26 USPQ2d 1389 (PTOBA&I 1993).

However, one must keep in mind that inherency, for both anticipation and obviousness determinations, must be certain. The mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency. That which may be inherent is not necessarily known, and anticipation or obviousness cannot be predicated on what is unknown. *In re Rijckaert*, 9 F.3d 1531, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). See also *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268-1269, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (quoting *In re Oelrich*, 666 F.2d 578, 581, 212 USQP 323, 326 (CCPA 1981)), and *Electro Medical Systems, S.A. v. Cooper Life Sciences, Inc.*, 34 F.3d 1048, 32 USPQ2d 1017 (Fed. Cir. 1994).

*Antoshkiw et al.*

Here that is simply not the case. Antoshkiw et al. do not inherently have the claimed molecular weight and vapor pressure. For example, one of the components of the stabilized carotenoid solution of Antoshkiw et al. is propylene glycol dicaprylate-dicaprate, which is a mixture of propylene glycol diesters of caprylic and capric acids, and thus can have a wide range of molecular weights depending upon the particular diesters that comprise the mixture. Thus, the claimed molecular weight range of 100 to 500 is not an inherent property of all propylene glycol dicaprylate-dicaprates, but rather those propylene glycol dicaprylate-dicaprates having this selected and particular range of molecular weights are suitable for use in the claimed solvent, formulation and aerosol spray system of the present invention. Those propylene glycol dicaprylate-dicaprates having a molecular weight outside of this range are not suitable for use in the present invention since they do not impart the desired properties to the claimed solvent, formulation and aerosol spray system of the present invention.

*Also argued that*

Likewise, the vapor pressure of a particular propylene glycol dicaprylate-dicaprate will depend upon the particular diesters that comprise the mixture and can vary widely. Thus, the claimed vapor pressure of less than 1.0 mm Hg is not an inherent property of all propylene glycol dicaprylate-dicaprates, but rather those propylene glycol dicaprylate-dicaprates having this selected and particular vapor pressure of less than 10. mm Hg are suitable for use in the claimed solvent, formulation and aerosol spray system of the present invention. Those propylene glycol dicaprylate-dicaprates having a vapor pressure greater than 1.0 mm Hg are not suitable for use in the present invention since they do not impart the desired properties to the claimed solvent, formulation and aerosol spray system of the present invention.

Thus, it is clear that the claimed molecular weight range and the claimed vapor pressure are not inherent features of all propylene glycol dicaprylate-dicaprates, but rather is the indicator of the propylene glycol dicaprylate-dicaprates suitable for use in the present invention.

Accordingly, reconsideration and withdrawal of this rejection is respectfully urged.

***Rejection Under 35 USC 103(a)***

Claims 1-7, 9-11, 21-26, 31-33 have been rejected under 35 USC 103(a) as being obvious over U.S. Patent No. 4,316,917 to Antoshkiw et al. in view of U.S. Patent No. 5,059,437 to Todd and Japanese Patent Publication No. 56089832. Antoshkiw et al. was said to teach as described above, and lacked the claimed glycerol tris(2-ethylhexanoate) and oleoresin of paprika. Todd was said to teach a color-stabilized paprika composition comprising propylene glycol esters of fatty acids and 48-49% oleoresin of paprika for the stabilization of the color of foods whilst the Japanese Patent was said to teach a stable oil-in-water emulsion containing 10 parts glycerol tris(2-ethylhexanoate). From this, it was concluded that it would have been obvious to modify the composition of Antoshkiw to include an oleoresin of paprika and glycerol tris(2-ethylhexanoate) to enhance the stability of the food product to which the claimed composition is added. This rejection is respectfully traversed and is believed to be obviated in view of the following remarks.

The courts have established that 35 U.S.C. § 103 obviousness is a question of law based on findings of fact relating to the prior art, the skill of the artisan, and objective considerations. See *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). A rejection of claims under 35 U.S.C. § 103 requires that the Examiner set forth a prima facie case of obviousness. See *In re Deuel*, 51 F.3d 1552, 1557, 34 USPQ2d 1210, 1214 (Fed. Cir. 1995). In order to set forth a prima facie case of obviousness based on a combination of references, the Examiner must have some teaching, suggestion, or motivation to combine the references. See *In re Geiger*, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987). In determining motivation, the Examiner may rely on the teachings of the references themselves, their relatedness to the field of the applicant's invention, and the knowledge of persons of ordinary skill in the field of the invention. See *In re Oetiker*, 977 F.2d at 1447, 24 USPQ2d at 1445-46; *In re Gorman*, 933 F.2d at 986-87, 18 USPQ2d at 1888; *In re Young*, 927 F.2d 588, 591, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991). However, the Examiner may not reconstruct the claimed invention from selected pieces of prior art absent some suggestion, teaching, or motivation in the

prior art to do so. *See, e.g., Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1051-52, 5 USPQ 2d 1434, 1438 (Fed. Cir. 1988). It is insufficient to select from the prior art the separate components of the inventor's combination, using the blueprint supplied by the inventor. *Interconnect Planning Corp v. Feil*, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985). Rather, the prior art must suggest to one of ordinary skill in the art the desirability of the claimed combination. *Fromsom v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1556, 225 USPQ 26, 31 (Fed. Cir. 1985). Rejecting patents solely by finding prior art corollaries for the claimed elements would permit an Examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention, which is an illogical and inappropriate process by which to determine patentability. *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457 (Fed. Cir. 1998).

Measuring a claimed invention against the standard established by § 103 requires the difficult, but critical, step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. *See, e.g., W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983). Close adherence to this methodology is particularly important where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." *Id.*

The best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding"); *In re Rouffet*, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("the Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select the references and combine them"); *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780,

1783 (Fed. Cir. 1992) (examiner can satisfy burden of obviousness in light of combination "only by showing some objective teaching [leading to the combination]"); *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion "essential" to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297, 227 USPQ 657, 667 (Fed. Cir. 1985) (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). *See also Graham*, 383 U.S. at 18, 148 USPQ at 467 ("strict observance" of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. *See, e.g., Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case, the Examiner has fallen into the hindsight trap in a failed effort to reconstruct the presently claimed invention.

Firstly, applicant would like to point out that the cited references are in a totally different field of use and are all directed to coloring and stabilizing agents for food products. In direct contrast, the present invention is directed to a novel solvent system operable over a wide range of temperatures and suitable for a wide range of applications, including use in an aerosol spray system; a novel formulation for incapacitating a person that comes into contact with the formulation by causing inflammation of the mucus membranes; and a novel aerosol spray system.

Secondly, there is no motivation to combine the references as suggested. As discussed above, Antoshkiw et al. is directed to a stabilized carotenoid solution for coloring foodstuffs comprising a coloring agent (cartenoid), a color stabilizer (anti-oxidant), a non-ionic surfactant to water disperse the coloring agent (25 to 35 weight %), and a solubilizer comprising 1 part glycerol monocaprylate to 1.5 to 3.5 parts of propylene glycol dicaprylate-dicaprate. Todd is directed to color stabilization of paprika for use in foodstuffs. On the other hand, the Japanese

Patent is directed to a stabile oil-in-water emulsion made by admixing an oil phase containing tris(2-ethylhexanoate) with a surfactant phase and then a two part addition of water with and without propylene glycol. One skilled in the art would simply not even consider stabilizers for oil-in-water emulsions as useful in a stabilized color solution.

And finally, even if the references were to be combined as suggested, they still would not result in or even suggest the present invention.

✓ Claim 1 is directed to non-lethal temporarily incapacitating formulation for use in an aerosol or spray application comprising an incapacitating agent and a solvent system of a glycerol tris(2-ethylhexanoate) and a mixture of propylene glycol esters of short chain fatty acids. Claim 2 provides that mixture of propylene glycol esters of short chain fatty acids is propylene glycol dicaprylate/caprate. Claim 9 provides for a list of suitable incapacitating agents. None of the cited references, either alone or in combination, describe or even suggest the subject matter of these claims. Nowhere does any of the cited references discuss or even suggest the possibility of a two component solvent system into which an incapacitating agent is dissolved, much less one for aerosol or spray use. Antoshkiw et al. require color stabilizers, non-ionic surfactants and a two part solubilizer just to place 2% of carotenoid into a solution. Obviously Antoshkiw et al. do not disclose a solvent able to readily disperse active ingredients therein. Todd uses a non-ionic surfactant to stabilize about an equal amount of a paprika so as to prevent color fading. Again, Todd does not suggest a two part component solvent system containing an incapacitating agent for aerosol or spray use. It would be laughable to one skilled in the art to consider trying to use the lotion or cream type formulation of the Japanese Patent in an aerosol or spray formulation. Additionally, the oleoresin of paprika used by Todd is that from a sweet pepper (e.g., Example 5) and does not contain the requisite amount of capsaicin to impart any incapacitating properties, even in the amounts used by Todd. In fact, one skilled in the art, upon reading Todd, would understand that the type of oleoresin of paprika of interest for Todd would be one with enhanced color and no capsaicin, since the resultant product is a highly colored but low taste product to add color to foodstuffs. In short, none of the cited references, either alone or



in combination disclose or suggest the claimed incapacitating formulation suitable for aerosol or spray use, a two part solvent system, or an incapacitating agent.

*Applicant argues that*  
Claims 3-7 depend from claim 1 and limit the amount of the solvent components to 20 to 80% by weight; 45 to 55% by weight; or equal amounts of the solvent system. The cited references are clearly not applicable for the reasons given above. *Applicant argues*  
Furthermore, the Japanese Patent, at best, discloses 10 % of glycerol tris(2-ethylhexanoate), which is well outside any of the claimed ranges.

Claims 10 and 11 depend from claim 1 and further limit the amount of incapacitating agent present in the formulation to 0.18% to 3% by weight and 1.4 to 1.5% by weight, respectively, of the solvent system. Again, the cited references are not applicable for the reasons given above. Furthermore, it is clear that the oleoresin of paprika in Todd cannot be considered an incapacitating agent since the Todd formulation requires about 48-49% of the oleoresin of paprika.

*Applicant argues that*  
Claims 21 and 31 are directed to a non-toxic solvent useful over a wide range of operating temperatures and comprising a mixture of propylene glycol dicaprylate/caprate and glycerol tris(2-ethylhexanoate). Again, for the reasons given above, none of the cited references, either alone or in combination, suggest or disclose the claimed two part solvent system with the unexpected wide range of operating temperatures.

*Applicant argues that*  
Claims 22-26 depend from claim 21 and claims 32-33 depend from claim 31 and further limit the amount of the solvent components to 20 to 80% by weight; 45 to 55% by weight; or equal amounts of the solvent system. The cited references are clearly not applicable for the reasons given above. Furthermore, the Japanese Patent, at best, discloses 10 % of glycerol tris(2-ethylhexanoate), which is well outside any of the claimed ranges.

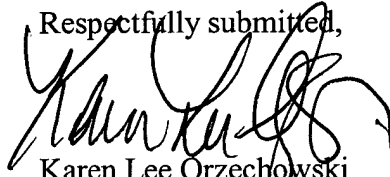
For the foregoing reasons, it is clear that none of the cited references, either alone or in combination, disclose or suggest the subject matter of the present invention as set forth in claims 1-7, 9-11, and 21-33. Accordingly, applicant respectfully urges and requests reconsideration and withdrawal of this rejection. Early and favorable action is earnestly solicited.

***Conclusion***

Should the Examiner have any questions, he is requested to contact the undersigned.

It is not believed that extensions of time or fees are required, beyond those, which may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned, and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 50-0548 and it is requested that the undersigned be notified in the event of such a charge to the Deposit Account.

Respectfully submitted,



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**CERTIFICATION OF FACSIMILE TRANSMISSION**

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Karen Lee Orzechowski